

## **§ 1002.41**

identify and locate first purchasers if the product is subject to this section by virtue of table 1 of §1002.1.

(b) Such information shall include:

(1) The name and mailing address of the distributor, dealer, or purchaser to whom the product was transferred.

(2) Identification and brand name of the product.

(3) Model number and serial or other identification number of the product.

(4) Date of sale, award, or lease.

(c) The information obtained pursuant to this section shall be forwarded immediately to the appropriate manufacturer of the electronic product, or preserved as prescribed in §1002.41.

[38 FR 28625, Oct. 15, 1973, as amended at 42 FR 18063, Apr. 5, 1977; 60 FR 48386, Sept. 19, 1995]

## **§ 1002.41 Disposition of records obtained by dealers and distributors.**

(a) Information obtained by dealers and distributors pursuant to §1002.40 shall immediately be forwarded to the appropriate manufacturer unless:

(1) The dealer or distributor elects to hold and preserve such information and to immediately furnish it to the manufacturer when advised by the manufacturer or the Director, Center for Devices and Radiological Health, that such information is required for purposes of section 359 of the Act; and

(2) The dealer or distributor, upon making the election under paragraph (a)(1) of this section, promptly notifies the manufacturer of such election; such notification shall be in writing and shall identify the dealer or distributor and the electronic product or products for which the information is being accumulated and preserved.

(b) Every dealer or distributor who elects to hold and preserve information required pursuant to §1002.40 shall preserve the information for a period of 5 years from the date of the sale, award, or lease of the product, or until the dealer or distributor discontinues dealing in, or distributing the product, whichever is sooner. If the dealer or distributor discontinues dealing in, or distributing the product, such information as obtained pursuant to §1002.40 shall be furnished at that time, or be-

## **21 CFR Ch. I (4-1-05 Edition)**

fore, to the manufacturer of the product.

[38 FR 28625, Oct. 15, 1973, as amended at 42 FR 18063, Apr. 5, 1977; 53 FR 11254, Apr. 6, 1988]

## **§ 1002.42 Confidentiality of records furnished by dealers and distributors.**

All information furnished to manufacturers by dealers and distributors pursuant to this part shall be treated by such manufacturers as confidential information which may be used only as necessary to notify persons pursuant to section 359 of the Act.

## **Subpart F—Exemptions From Records and Reports Requirements**

### **§ 1002.50 Special exemptions.**

(a) Manufacturers of electronic products may submit to the Director a request, together with accompanying justification, for exemption from any requirements listed in table 1 of §1002.1. The request must specify each requirement from which an exemption is requested. In addition to other information that is required, the justification must contain documented evidence showing that the product or product type for which the exemption is requested does not pose a public health risk and meets at least one of the following criteria:

(1) The products cannot emit electronic product radiation in sufficient intensity or of such quality, under any conditions of operation, maintenance, service, or product failure, to be hazardous;

(2) The products are produced in small quantities;

(3) The products are used by trained individuals and are to be used by the same manufacturing corporation or for research, investigation, or training.

(4) The products are custom designed and used by trained individuals knowledgeable of the hazards; or

(5) The products are produced in such a way that the requirements are inappropriate or unnecessary.

(b) The Director may, subject to any conditions that the Director deems necessary to protect the public health, exempt manufacturers from all or part